ADVERSE DRUG REACTION REPORT FORM

PATIENT DATA

Initials	Age	Sex F □ M □	Weight

SUSPECT DRUG(S) INFORMATION

Invented name	Indications	Daily dose	Route of administration	Therapy start date	Therapy end date

ADVERSE DRUG REACTION INFORMATION

<table>
<tr><td rowspan="2">Description:</td><td>Reaction start date</td><td>Reaction end date</td></tr>
<tr><td colspan="2">Outcome:

□ recovered without sequelae

□ recovering

□ recovered with sequelae

□ unknown/no data</td></tr>
<tr><td colspan="3">Did reaction abate after stopping the drug? □ Yes □ No □ No data

Did re action reappear after reintroduction? □ Yes □ No □ No data</td></tr>
<tr><td rowspan="2">Type of adverse reaction</td><td colspan="2">□ non-serious</td></tr>
<tr><td>□ serious</td><td>□ death

□ life threatening

□ involved persistent or significant disability or incapacity

□ involved or prolonged patient hospitalisation

□ other medically important</td></tr>
</table>

ADDITIONAL INFORMATION

Concomitant drug(s)	Indication	Daily dose(s)	Route of administration	Therapy start date	Therapy end date
Medical history, allergies, environmental risk factors, other risk factors					
Pregnancy – Yes □ No □ If yes – week of pregnancy …….					

REPORTER DETAILS

Name and surname …….. Specialty.....

Address ……. Tel no.....

Date …… Signature.....

Filled form please send immediately to the fax no +48 ***22 344 74 10 .*** *Original please send by mail to: USP Zdrowie Sp. z o.o.,*
ul Poleczki 35, 02-81 Warszawa or give it to the company representative.

Personal data processing notice

Pursuant to Article 13(1) and 13(2) of Regulation 2016/679 of the European Parliament and of the Council (EU) of 27 April 2016 the on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC ("GDPR"), please be informed that:

1. USP Pharmacia Sp. z o.o. in Warsaw, ul. Ziębicka 40, zip code 50-507, is the controller of your personal data.

2. Your personal data will be processed for purposes related to compliance with the pharmacovigilance obligation arising from the Polish Pharmaceutical Law of 6 September 2001 (Article 6(1)(c) of the GDPR). For special categories of personal data, e.g. health-related data, USP Pharmacia processes your data on the ground of necessity in connection with public interest in the area of public health, such as assurance of high quality standards and safety of cosmetics (Article 9(2)(i) of the GDPR).

3. The individuals obligated to report adverse effects of medicinal products are required to give their personal data under applicable provisions of the Polish Pharmaceutical Law of 6 September 2001 and other legislation.

4. Other individuals give their data voluntarily but they must do this for their report to be accepted.

5. Your personal data will be provided to government bodies authorised under applicable laws (e.g. drug registration offices).

6. Your personal data shall be retained for a period as required under applicable laws.

7. You have a right to access your data, a right to data rectification, a right to restriction of processing and a right to object.

8. You have a right to lodge a complaint to a competent supervisory authority whenever you believe that the processing of your personal data is in breach of the GDPR.